EXHIBIT J

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/909,058	06/23/2020	Michael FRANCIS	182.0001-US02	1508

92049 7590 07/28/2020

J.A. Lindeman & Co. PLLC
3190 Fairview Park Drive
Suite 1070
Falls Church, VA 22042

EXAMINER	
SONG, JIANFENG	

ART UNIT	PAPER NUMBER
1613	

NOTIFICATION DATE	DELIVERY MODE
07/28/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jeff.lindeman@jalindeman.com
mail@jalindeman.com
yamini.anand@clarivate.com

Office Action Summary	Application No. 16/909,058	Applicant(s) FRANCIS et al.	
	Examiner JIANFENG SONG, Ph.D.	Art Unit 1613	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☑ An election was made by the applicant in response to a restriction requirement set forth during the interview on 21 July 2020; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) 16-30 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-15 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☑ Claim(s) 1-15 are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 06/23/2020.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to an implantable ligament and tendon repair device, classified in A61L27/26.

II. Claims 16-30, drawn to a method for facilitating repair of a damaged tendon, classified in A61L27/386.

The inventions are independent or distinct, each from the other because:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product, for example, implant from collagen alone or biodegradable polymer alone.

Restriction for examination purposes as indicated is proper because all the inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and/or examination burden if restriction were not required because one or more of the following reasons apply:

A different field of search is required.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 or pre-AIA 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product or apparatus claims and process claims. Where applicant elects claims directed to the product/apparatus, and all product/apparatus claims are subsequently found allowable, withdrawn process claims

that include all the limitations of the allowable product/apparatus claims should be considered for rejoinder. All claims directed to a nonelected process invention must include all the limitations of an allowable product/apparatus claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product/apparatus claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product/apparatus are found allowable, an otherwise proper restriction requirement between product/apparatus claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product/apparatus claim will not be rejoined. See MPEP § 821.04. Additionally, in order for rejoinder to occur, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product/apparatus claims. **Failure to do so may result in no rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be corrected in compliance with 37 CFR 1.48(a) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. A request to correct inventorship under 37 CFR 1.48(a) must be accompanied by an application data sheet in accordance with 37 CFR 1.76 that identifies each inventor by his or her legal name and by the processing fee required under 37 CFR 1.17(i).

During a telephone conversation with Jeffrey Lindeman on 07/21/2020 a provisional election was made without traverse to prosecute the invention of invention group I, claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 16-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-30 are pending, claims 1-15 are under examination.

Priority

Acknowledge is made that this application is a Continuation Application of U.S. Application No. 16/818,241, filed March 13, 2020; which is a Divisional Application of U.S. Application No. 16/152,963, filed October 5, 2018; which is a Continuation Application of PCT International Application No. PCT/US2018/000119, filed May 15, 2018; which claims priority to U.S. Provisional Patent Application 62/603,026, filed May 16, 2017.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 06/23/2020 is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 of this title, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5-10 and 15 are rejected under 35 U.S.C. 103 as being unpatentable over Francis et al. (US20160022865) in view of Qiao et al. ("Composition and in Vitro Evaluation of Nonwoven Type I Collagen / Poly-dl-lactic Acid Scaffolds for bone Regeneration", J. Funct. Biomater. 2015, 6, 667-686; cited in IDS) and Hossainy et al. (US20150081000).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Francis et al. teaches a scaffold comprising an **aligned fiber**. The invention further relates to a scaffold comprising one or more **electrospun** fibers wherein a fast Fourier transform (FFT) analysis result of the fibers have adjacent major peaks with about 180? Apart from each other. Methods for promoting differentiation of stem cells into osteoblasts, chondrocytes, **ligament or tendon**, the method comprising culturing the cells on the scaffold or aligned fiber in conditions suitable for the cell differentiation (abstract). In one embodiment, the nanofiber have diameter **from 50nm to 1000nm** (page 3, [0033]). ***This teaches applicant's claim 15***. In some embodiments, the scaffold may be in the form of **one or more elongated sheets** (page 4, [0044-0045]; claims 1 and 23).**The scaffold includes fiber from collagen, polylactic acid (encompassing PLLA, PDLA and PDLLA), poly (glycolic acid) , PLGA, and mixture thereof** (page 4, [0040]; claims 1, 12-16-17). ***This teaches applicant's claims 6-10.*** In some embodiment, the electrospun fiber is crosslinked chemically or by dehydrothermal such as heat-promoted condensation (page 5, [0060]; claim 1, 18). In some embodiments, the biocompatible matrix is prepared into a form of an elongated roll, an elongated sheet, a composite of multiple layers of sheets (page 4, [0044]). ***This teaches applicant's claim 5.*** In some embodiments, the elongated sheet described herein may have an **average thickness** of about 1000 μm or less, 900 μm or less, 800 μm or less, 700 μm or less, 600 μm or less, 500 μm or less, **400 μm** or less, 300 μm or less, **200 μm** or less, 100 μm or less, 50 μm or less, 20 μm or less, or 10 μm or less. In one aspect, the elongated sheet described herein may have an average thickness of about 1000 μm or more, 900 μm or more, 800 μm or more, 700 μm or more, 600 μm or more, 500 μm or more, 400 μm or more, 300 μm or more, 200 μm or more (page 4,

[0046]). ***This teaches applicant's claim 3***. In some embodiments, the biocompatible matrix includes but is not limited to, bone graft implants, synthetic bone graft materials in forms of particulates, sheet, or blocks, **tendon and/or ligament in bone tunnels**, prosthetic implant (page 5, [0048]). Suitable biocompatible matrices include, but are not limited to, porous biocompatible scaffolds into which bone cells or progenitor cells may migrate. Osteogenic or chondrogenic cells, i.e., cells involved in the process of deposition of new bone material or cartilagenous material, respectively, can often attach to such porous biocompatible matrices, which can then serve as scaffolding for bone and cartilage tissue growth (page 5, [0049]).

Qiao et al. teaches Poly-dl-lactic acid (PDLLA) was blended with type I collagen to attempt to overcome the instantaneous gelation of electrospun collagen scaffolds in biological environments. Scaffolds based on blends of type I collagen and PDLLA were investigated for material stability in cell culture conditions (37 °C; 5% CO2) in which post-electrospinning glutaraldehyde crosslinking was also applied. The resulting wet-stable webs were cultured with **bone marrow stromal cells** (HBMSC) for five weeks. Scanning electron microscopy (SEM), confocal laser scanning microscopy (CLSM), Fourier transform infra-red spectroscopy (FTIR) and biochemical assays were used to characterize the scaffolds and the consequent cell-scaffold constructs. To investigate any electrospinning-induced denaturation of collagen, identical PDLLA/collagen and PDLLA / gelatine blends were electrospun and their potential to promote osteogenic differentiation investigated. PDLLA/collagen blends with w/w ratios of 40/60, 60/40 and 80/20 resulted in satisfactory wet stabilities in a humid environment, although chemical crosslinking was essential to ensure long term material cell culture. Scaffolds of

PDLLA/collagen at a 60:40 weight ratio provided the greatest stability over a five-week culture period. The PDLLA/collagen scaffolds promoted greater cell proliferation and osteogenic differentiation compared to HMBSCs seeded on the corresponding PDLLA/gelatine scaffolds, suggesting that any electrospinning-induced collagen denaturation did not affect material biofunctionality within 5 weeks *in vitro (abstract).* The as-spun Fiber diameter for PDL40 is about 1014nm, PDL60 is about 668±23.4nm and PDL80 is about 330nm; the after incubation Fiber diameter for PDL40 is about 1303nm, PDL60 is about 770nm and PDL80 is about 472nm (page 670, Table 1). PDLLA (57KDa) is from Purac, and Type I collagen was acid–extracted (page 679-680, Experimentation Section). The scaffold is **vacuum drying** in a desiccator (page 681, last paragraph; page 682, first paragraph). Incorporating high molecular weight PDLLA polymer with type I collagen followed by GD **crosslinking** produced water stable electrospun fibrous scaffolds (page 682, Conclusion section).

Hossainy et al. teaches a braided polymeric scaffold, made at least in part from a bioresorbable material is deployed on a catheter that uses a push-pull mechanism to deploy the scaffold. A drug coating is disposed on the scaffold. A plurality of scaffold segments on a catheter is also disclosed (abstract). Following formation of a fiber by extrusion, the fiber **may be annealed** to modify the crystallinity of the polymer. The fiber may be heated to a temperature between Tg and Tm of the polymer for 5 min to 1 hr, 1 hr to 5 hr, 5 hr to 20 hr. The increase in crystallinity increases the tensile strength and modulus of the fiber. The fibers may be under tension during the annealing process to prevent shortening of the fibers. The crystallinity may be increased by the annealing

from less than 10% or 20% to 20% to a higher crystallinity within any of the ranges disclosed herein ([0241]).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The difference between the instant application and **Francis et al.** is that **Francis et al.** do not expressly teach annealed sheet; percentage of collagen and polymer; This deficiency in **Francis et al.** is cured by the teachings of **Qiao et al. and** Hossainy et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to modify the invention of **Francis et al.,** as suggested by **Qiao et al. and** Hossainy et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to have annealed fiber because it is advantage to increase in crystallinity, the tensile strength and modulus of the fiber during the annealing process as suggested by Hossainy et al. Therefore, it is obvious for one of ordinary skill in the art to have annealed fiber and produce instant claimed invention with reasonable expectation of success.

One of ordinary skill in the art would have been motivated to have about 10-35% (20-35%, 27.5-32.5%) of collagen and 65 to 90% (65-80%, 67.5-72.5%) of polymer in the biopolymer fiber because this is optimization through routing experimentation or

under prior art conditions. MPEP 2144.05. Under guidance from Qiao teaching 20-60% of collagen and 40-80% of polymer for biopolymer fiber, it is obvious for one of ordinary skill in the art to have about 10-35% (20-35%, 27.5-32.5%) of collagen and 65 to 90% (65-80%, 67.5-72.5%) of polymer in the biopolymer fiber and produce instant claimed invention with reasonable expectation of success.

Regarding claim 1, Francis et al. teaches the biocompatible matrix in the form of tendon and ligament,

Regarding telocollagen in claim 1-2, Qiao et al. teaches Type I collagen was acid–extracted, which is telocollagen according to applicant's specification (page 10). Thus, telocollagen is suitable type I collagen for biopolymer fiber, and it is obvious for one artisan in the art to use telocollagen for biopolymer finer. MPEP 2144.05.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 4 and 11-14 are rejected under 35 U.S.C. 103 as being unpatentable over Francis et al. (US20160022865) in view of Qiao et al. ("Composition and in Vitro Evaluation of Nonwoven Type I Collagen / Poly-dl-lactic Acid Scaffolds for bone Regeneration", J. Funct. Biomater. 2015, 6, 667-686; cited in IDS), Hossainy et al. (US20150081000), as applied for the above 103 rejection for claims 1-3, 5-10 and 15, further in view of Buehrer et al. (US20090098175), Van Kampen et al. (US20110224702), HE et al. (US20160279301), Yang et al. (US20160199541) and Ratcliffe (US20100145367).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Francis et al., Qiao et al. and Hossainy et al. teaching have already been discussed in the above 103 rejections and are incorporated herein by reference.

Buehrer et al. teaches inducing growth factor to a surface of an implant, the composition comprising a peptide having binding affinity for a surface material of an implant coupled to a peptide having binding affinity for a fibrous connective tissue-inducing growth factor. Methods are provided for delivering fibrous connective tissue-inducing growth factor GDF-7 in an amount effective to promote fibrous connective tissue repair and fibrous connective tissue formation (abstract). The implant is selected from the group consisting of a: suture, biodegradable sponge, surgical mesh, **tendon wrap, ligament wrap**, prosthesis for fibrous connective tissue, collagen scaffold, collagen thread, composite collagen felt, synthetic graft, ligament graft, ligament prostheses, ligament augmentation device and scleral buckle (claims 10-14).

Van Kampen et al. teaches a tendon repair implant for treatment of a partial thickness tear in the supraspinatus tendon of the shoulder is provided. The implant may incorporate features of rapid deployment and fixation by arthroscopic means that compliment current procedures; tensile properties that result in desired sharing of anatomical load between the implant and native tendon during rehabilitation; selected porosity and longitudinal pathways for tissue in-growth; sufficient cyclic straining of the implant in the longitudinal direction to promote remodeling of new tissue to tendon-like tissue; and, may include a bioresorbable construction to provide transfer of additional load to new tendon-like tissue and native tendon over time (abstract). It is desirable in some situations to generate as much tissue as possible within anatomical constraints. In some cases where a tendon is degenerated or partially torn, tendon loads are relatively low during early weeks of rehabilitation. For example, the load may be about 100 N. The strain in the tendon due to the load during rehabilitation can be about 2%. In some of these cases, the tendon repair implant can be designed to have an ultimate tensile strength of at least about 2 MPa. **The tensile modulus may be designed to be no more than about 50 MPa and no less than about 5 MPa.** The compressive modulus may be designed to be at least about 0.2 MPa. With a tensile modulus of 5 MPa, in order for the implant to strain 2% in conjunction with the degenerated tendon, the stress on the implant will be about 1.0 MPa. With an ultimate tensile strength of 2 MPa, the strength of the sheet-like structure of the implant when first implanted will be about two times the expected loads. With a cross-sectional area of 20 mm2, the load on the implant will be 20 N. Thus, from a load sharing perspective, the implant will carry about 20% of the load to experience 2% strain ([0057]).

HE et al. teaches a hydrophilic electrospinning biological composite stent material used for tissue regeneration and a preparation method and an application thereof are provided. An aqueous solution of Fibrinogen, L-arginine or hydrochloride thereof and a P(LLA-CL) solution are blended and an electrospinning technology is used to prepare the biological composite stent material. The biological composite stent material has an equilibrium contact angle that is less than 55 degree., is hydrophilic and has a good application prospect in repairing body tissue defects (abstract). The electrospinning membranes had a thickness of 250-300 um, a contact angle of less than 5 degree and a **tensile strength of 10-20 MPa**. The obtained membranous material was cut into a rectangular or square shape and rolled up for 3-4 laps to form a cylinder with a diameter of 3-5 mm and a length of 3-10 mm. After sterilization using 25 KGy electron beam, the obtained material was used as a substitute for canine Achilles tendon and anterior cruciate ligament ([0067]).

Yang et al. teaches the implants and devices comprising a polymer or polymer network in the form of ligament or tendon (abstract; [0016, 0090]). The implant scaffold has peak stress from about 1 Mpa to about 45 Mpa ([0098]; claims 18 and 30).

Ratcliffe teaches Synthetic structures for fibrous soft tissue repair include a planar fibrillar structure which exhibits mechanical properties comparable to those of human fibrous soft tissue. In embodiments, the fibrillar structure possesses at least one secured folded edge portion (abstract). In embodiments, the fibrillar structure exhibits a stiffness of from about 20 to about 80 Newtons per millimeter (N/mm), and exhibits a failure strain at from about 105% to about 150% of its original length. The implant

comprising planar fibrillar structure exhibiting the mechanical properties of a human tendon ([0008]; claims 1, 11, 15 and 18).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The difference between the instant application and Francis et al. is that Francis et al. do not expressly teach wrap and characteristic in claims 11-14. This deficiency in Francis et al. is cured by the teachings of Buehrer et al., Van Kampen et al., HE et al., Yang et al. and Ratcliffe.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art before the effective filing date of the claimed invention to modify the invention of Francis et al., as suggested by Buehrer et al., Van Kampen et al., HE et al., Yang et al. and Ratcliffe, and produce the instant invention.

One of ordinary skill in the art would have been motivated to prepare ligament and tendon repair device in the form of a wrap because wrap is suitable form for tendon and ligament implant as suggested by Buehrer et al. MPEP 2144.07. The selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S.

327, 65 USPQ 297 (1945). Therefore, it is obvious for one of ordinary skill in the art to prepare ligament and tendon repair device in the form of a wrap and produce instant claimed invention with reasonable expectation of success.

One of ordinary skill in the art would have been motivated to have tensile strength of about 4 to 16MPa, modulus of elasticity of about 35-750 MPa, peak stress about 11 to 15.2 MPa and strain of failure 50-200% because this is optimization under prior art condition or through routing experimentation. MPEP 2144.05. Under guidance from Van Kampen et al. teaching the tendon repair implant can be designed to have an ultimate tensile strength of at least about 2 MPa and the tensile modulus (modulus of elasticity) may be designed from 5-50MPa; HE et al. teaching electrospinning biological composite stent material used for tissue regeneration having a tensile strength of 10-20 MPa for tendon repair; Yang et al. teaching the implants in the form of ligament or tendon with peak stress from about 1 Mpa to about 45 Mpa; Ratcliffe teaching implant comprising planar fibrillar structure exhibiting the mechanical properties of a human tendon with a failure strain from about 105% to about 150% of its original length; it is obvious for one of ordinary skill in the art to have tensile strength of about 4 to 16MPa, modulus of elasticity of about 35-750 MPa, peak stress about 11 to 15.2 MPa and strain of failure 50-200% and produce instant claimed invention with reasonable expectation of success.

Regarding claim 14, prior art is silent regarding strain of failure “as tensile tested at 1 mm/s in hydrated condition”, and it is the examiner’s position that the prior art value about 105% to about 150% would not change significantly so that the prior art failure

strain still inside or overlapping with the claimed range of 50-200% in the absence of evidence to the contrary.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art before the effective filing date of the claimed invention, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP §§ 706.02(l)(1) - 706.02(l)(3) for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-15 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 10617787. Although the claims at issue are not identical, they are not patentably distinct from each other because the reference patent teaches each limitation of applicant's claimed invention.

Claims 1-15 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 29-30 of copending Application No. 16818241 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the reference application teaches instant each limitation of claimed implant.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JIANFENG SONG, Ph.D. whose telephone number is (571)270-1978. The examiner can normally be reached on M-F 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian-Yong Kwon can be reached on (571)272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JIANFENG SONG/
Primary Examiner, Art Unit 1613